CLAIMS

1. An extract of the plant Calotropis procera, characterized in that said extract has a pharmacological activity, in particular an anti-poisonous activity.

2. An extract according to claim 1 obtained using an extraction procedure, comprising the steps of:

a) extracting the starting material of said Calotropis procera plant, said starting material being selected among fruits, aerial parts subterranean parts, and their mixtures, in an aliphatic alcohol, by dissolving the starting material in said alcohol thereby obtaining a suspension of said material in said alcohol, stirring said suspension, and filtering said suspension by fritted glass thereby obtaining a first filtrate and a first solid part;

b) extracting said first solid part in an aliphatic alcohol thereby obtaining a second filtrate and a second solid part;

c) combining said first and said second filtrate thereby obtaining a combined filtrate, and evaporating said combined filtrate under vacuum thereby obtaining said extract.

3. An extract according to claim 1 obtained using a extraction procedure comprising the steps:

a) grinding the starting material of leaf blades, stems, barks and roots of Calotropis procera to give a fine powder of the plant,

b) extracting the powder of step a) with dichloromethane for at least 6, 12, 18 or preferably 24 hours using a soxhlet extractor,

c) decanting the dichloromethane of step b), and evaporating the filtrate, after filtration, to obtain a gum.

4. An extract according to claim 1 obtained using a extraction procedure comprising the steps:

a) grinding the starting material of leaf blades, stems, barks and roots of Calotropis procera give a fine powder of the plant,

b) extracting the powder of step a) with dichloromethane for at least 6, 12, 18 or preferably 24 hours using a soxhlet extractor,

c) decanting the dichloromethane of step b), and evaporating the filtrate, after filtration, to obtain a gum,

d) extracting the residue of step c) with methanol for at least 6, 12, 18 or preferably 24 hours using a soxhlet extractor,

e) decanting the methanol of step d), evaporating the filtrate, after filtration, to obtain a gum,

f) subjecting the gum of step e) to column chromatography using flash silica gel and dichloromethane-methanol as solvent, and

g) collecting a first fraction and evaporating of the said fraction to obtain a gum having biologically active components.

5. An extract according to claim 1 obtained using a extraction procedure comprising the steps:

a) grinding the starting material of leaf blades, stems, barks and roots of Calotropis procera give a fine powder of the plant,

b) extracting the powder of step a) with dichloromethane for at least 6, 12, 18 or preferably 24 hours using a soxhlet extractor,

c) decanting the dichloromethane of step b), and evaporating the filtrate, after filtration, to obtain a gum,

d) extracting the residue of step c) with methanol for at least 6, 12, 18 or preferably 24 hours using a soxhlet extractor,

e) decanting the methanol of step d), evaporating the filtrate, after filtration, to obtain a gum,

f) subjecting the gum of step e) to column chromatography using flash silica gel and dichloromethane-methanol as solvent,

g) collecting a first fraction, having biologically active components,

h) applying the concentrated fraction of step g) to column chromatography using flash silica gel and hexane-acetone as solvent to give two fractions, and

i) washing the column after step h) with methanol to give a third fraction, having biologically active components.

6. A composition comprising:
- an extract of Calotropis procera according to any of claims 1 to 5, and
- at least one therapeutic compound and/or a physical treatment that exerts relevant, detrimental side effects on normal, non-cancer related cells, tissues or organs.

7. A product containing
- an extract of Calotropis procera, according to claim 1 to 5, and
- at least one therapeutic compound and/or a physical treatment that exerts relevant, detrimental side effects on normal, non-cancer related cells, tissues or organs
as a combined preparation for simultaneous, separate or sequential administration to a subject.

8. A composition according to claim 6 or a product according to claim 7 where one of the said extracts comprises at least two active compounds selected from the group comprising asclepin, calactin, vorusharin, calotropin, calotropagenin, uzarigenin, calotoxin, usharin and usharidin.

9. A composition according to claims 6 and 8, or a product according to claim 7 and 8 wherein one of the said extracts comprises at least one of the compounds which are represented in Table 1.

10. A composition according to any of claims 6, 8 and 9 or a product according to any of claims 7 to 9 wherein the weight ratio of extract: therapeutic compound is in the range 0.001 : 1 to 1000 : 1.

11. A composition according to any of claims 6, and 8 to 10, or a product according to any of claims 7 to 10, for use as a medicament.

12. A composition according to any of claims 6, and 8 to 10, or a product according to any of claims 7 to 11, for use as a medicament for the treatment of cancer.

13. A composition or product according to claim 12, wherein said cancer is selected from the group comprising breast cancer, lymphoma, sarcoma, pancreatic cancer, melanoma, colorectal cancer, glioma, non small cell lung cancer, small cell lung cancer, skin cancer, bone cancer, ovarian cancer, CNS cancer, renal cancer, bladder cancer, head and neck cancer, prostate cancer, liver cancer, hematological cancers.

14. A composition according to any of claims 6, and 8 to 13 or a product according to any of claims 7 to 13 further comprising one or more additional therapeutic compounds.

15. A composition according to any of claims 6, and 8 to 14, or a product according to any of claims 7 to 14, wherein said therapeutic compound(s) is an anti-cancer agent.

16. A composition according to any of claims 6, and 8 to 15, or a product according to any of claims 7 to 14, wherein said therapeutic compound is selected from the group comprising adriamycin, alkeran, ara-c, bleomycin, biCNU, busulfan, CCNU, carboplatinum, cisplatinum, cyclophosphamide, cytoxan, daunorubicin, DTIC, 5-FU, fludarabine, gemcitabine (gemzar), herceptin, hexamethylmelamine, hydrea, idarubicin, ifosfamide, irinotecan (camptosar, CPT-11), leustatin, methotrexate, mithramycin, mitomycin, mitoxantrone, muphoran, navelbine, nitrogen mustard, oxaliplatine, rituxan, STI-571, streptozocine, taxol, taxotere, topotecan (hycamtin), velban, vincristine, VP-16, xeloda (capecitabine), or zevelin.

17. A composition according to any of claims 6, and 8 to 16, or a product according to any of claims 7 to 16, wherein said therapeutic compound is selected from the group comprising adriamycine, vincristine, camptothecin and oxaliplatin.

18. A composition according to any of claims 6, and 8 to 17, or a product according to any of claims 7 to 17, wherein said therapeutic compound(s) is a cytotoxic antibody or a fragment thereof.

19. A composition according to any of claims 6, and 8 to 18, or a product according to any of claims 7 to 18, wherein said therapeutic compound(s) is a cytotoxic hormone or a fragment thereof.

20. A composition according to any of claims 6, and 8 to 19, or a product according to any of claims 7 to 19, wherein said therapeutic compound(s) is a cytotoxic peptide or a fragment thereof.

21. A composition according to any of claims 6, and 8 to 20 further comprising a pharmaceutically acceptable carrier or a product according to any of claims 7 to 20 wherein the composition and/or therapeutic compound(s) further comprises a pharmaceutically acceptable carrier.

22. Use of an extract of Calotropis procera according to claim 1 to 5 for the preparation of a medicament for alleviating the side effects of one or more therapeutic compounds.

23. Use of an extract of Calotropis procera according to claim 1 to 5 for the preparation of a medicament for increasing the dose administered to an individual of one or more therapeutic compounds.

24. Use of an extract according to claims 22 and 23 wherein said therapeutic compound(s) has anti-cancer activity.

25. Use of an extract according to any of claims 22 to 24 wherein said therapeutic compound(s) is selected from the group comprising adriamycin, alkeran, ara-c, bleomycin, biCNU, busulfan, CCNU, carboplatinum, cisplatinum, cyclophosphamide, cytoxan, daunorubicin, DTIC, 5-FU, fludarabine, gemcitabine (gemzar), herceptin, hexamethylmelamine, hydrea, idarubicin, ifosfamide, irinotecan (camptosar, CPT-11), leustatin, methotrexate, mithramycin, mitomycin, mitoxantrone, muphoran, navelbine, nitrogen mustard, oxaliplatine, rituxan, STI-571, streptozocine, taxol, taxotere, topotecan (hycamtin), velban, vincristine, VP-16, xeloda (capecitabine), or zevelin.

26. Use of an extract according to claims 22 and 25 wherein said therapeutic compound(s) is selected from the group comprising adriamycine, vincristine, camptothecin and oxaliplatin.

27. Use of an extract according to any of claims 22 to 26 wherein said therapeutic compound(s) is a cytotoxic antibody or a fragment thereof.

28. Use of an extract according to any of claims 22 to 27 wherein said therapeutic compound(s) is a cytotoxic hormone or a fragment thereof.

29. Use of an extract according to any of claims 22 to 28 wherein said therapeutic compound(s) is a cytotoxic peptide or a fragment thereof.

30. Use of an extract according to any of claims 22 to 29 wherein said therapeutic compound(s) is therapeutic radiation.

31. Use of an extract according to any of claims 22 to 30 wherein said extract comprises at least two active compounds selected from the group comprising asclepin, calactin, vorusharin, calotropin, calotropagenin, uzarigenin, calotoxin, usharin and usharidin.

32. Use of an extract according to any of claims 22 to 31 wherein said extract further contains at least one of the compounds which are represented in Table 1.

33. Use of an extract according to any of claims 22 to 32 wherein said extract is administered prior to said therapeutic compound(s).

34. Use of an extract according to any of claims 22 to 33 wherein said extract is administered after said therapeutic compound(s).

35. Use of an extract according to any of claims 22 to 34 wherein said extract is administered at the same time as said therapeutic compound(s).

36. Use of an extract according to claim 22 to 35 wherein the weight ratio of extract: therapeutic compound is in the range 0.001 :1 to 1000:1.

37. An extraction process for obtaining an extract having biologically active components comprising the steps of:

a) extracting the starting material of said Calotropis procera plant, said starting material being selected among fruits, aerial parts, subterranean parts, and their mixtures, in an aliphatic alcohol, by dissolving the starting material in said alcohol thereby obtaining a suspension of said material in said alcohol, stirring said suspension; and filtering said suspension by fritted glass thereby obtaining a first filtrate and a first solid part;

b) extracting said first solid part in an aliphatic alcohol thereby obtaining a second filtrate and a second solid part;

c) combining said first and said second filtrate thereby obtaining a combined filtrate; and

d) evaporating said combined filtrate under vacuum thereby obtaining said extract.

38. An extraction process for obtaining a several extracts having biologically active components present substantially in the leaves, stems, barks and roots of Calotropis procera, which comprises the following steps:

a) grinding the starting material of leaf blades, stems, barks and roots of Calotropis procera give a fine powder of the plant,

b) extracting the powder of step a) with dichloromethane for at least 6, 12, 18 or preferably 24 hours using a soxhlet extractor, and

c) decanting the dichloromethane of step b), and evaporating the filtrate, after filtration, to obtain a gum.

39. An extraction process according to claim 38 further comprising the steps of:

d) extracting the residue of step c) with methanol for at least 6, 12, 18 or preferably 24 hours using a soxhlet extractor,

e) decanting the methanol of step d), evaporating the filtrate, after filtration, to obtain a gum,

f) subjecting the gum of step e) to column chromatography using flash silica gel and dichloromethane-methanol as solvent, and

g) collecting a first fraction having biologically active components,and evaporating the eluent to obtain said extract.

40. An extraction process according to claims 38 and 39, further comprising the steps of

h) applying fraction of step g) to column chromatography using flash silica gel and hexane-acetone as solvent to give two fractions,

i) washing the column after step h) with methanol to give a third fraction, having biologically active components

41. A process according to any of claims 38 to 40, wherein step b) is performed at a working temperature of between 20 and 80°C.

42. A process according to any of claims 38 to 41, wherein said step b) is repeated between one and five times.

43. A process according to any of claims 38 to 40, wherein the duration of step b) is between 4 hours and 48 hours.

44. A process according to any of claims 38 to 43, wherein the solid phase of step d) is silica gel.

45. A process according to any of claims 38 to 44, wherein the eluent of step d) is a binary eluent, the ratio between the two components of the eluent being between 100:0 to 0:100.

46. A process according claim 45, wherein the components of said binary eluent comprise an alcoholic solvent and a non polar solvent.

47. A process according to any of claims 39 to 46, wherein step e) is performed at a working temperature of between 20 and 50°C.

48. A process according to any of claims 39 to 45, wherein the solid phase of step f) is silica gel.

49. A process according to any of claims 39 to 45, wherein the eluent of step f) is a binary eluent, the ratio between the two components of eluent being between 100:0 to 0:100.

50. A process according to claim 49, wherein the components of the binary eluent are a non-polar and a more polar solvent.

51. A process according claim 50, wherein the ratio between the two components of eluent, non-polar:polar, is between 50:50 and 100:0.

52. A process according to any of claims 40 to 49, wherein the solvent of step h) is methanol.

53. A process according to any of claims 39 to 52, wherein step e) is performed at a working temperature of between 20 and 50°C.

54. Active extract isolated from the process according to any of claims 37 to 53.

55. Use of an active extract according to claim 54 as a medicament.

56. Use of an active extract according to claim 54 for the preparation of a medicament in the treatment of cancer.

57. A method for treating cancer comprising administering to an individual in need of such treatment a pharmaceutical composition according to any of claims 6, and 8 to 21, or a product according to any of claims 7 to 21.

58. A method according to claim 57, wherein said cancer is selected from the group comprising breast cancer, lymphoma, sarcoma, pancreatic cancer, melanoma, colorectal cancer, glioma, non small cell lung cancer, small cell lung cancer, skin cancer, bone cancer, ovarian cancer, CNS cancer, renal cancer, bladder cancer, head and neck cancer, prostate cancer, liver cancer, hematological cancers.

59. A composition according to any of claims 6, and 8 to 21, or product according to any of claims 7 to 21, wherein the therapeutic compound is radiation.

60. A kit comprising a container in which an extract of Calotropis procera according to any of claims 1 to 5 is present, and a container in which a therapeutic compound is present.